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09/697,306	10/27/2000	James F. McGuckin JR.	10546/53003	4213

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FAY KAPLUN & MARCIN, LLP
150 BROADWAY, SUITE 702
NEW YORK, NY 10038

EXAMINER	
DAWSON, GLENN K	
ART UNIT	**PAPER NUMBER**
3731	

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Commissioner for Patents

Please see the attached communication.

Glenn K Dawson
Primary Examiner
Art Unit: 3731

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/697,306
Filing Date: October 27, 2000
Appellant(s): MCGUCKIN, JAMES F.

Oleg F. Kaplun
For Appellant

Supplemental
EXAMINER'S ANSWER

This is in response to the reply brief filed 01-14-2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the arguments do not outline why claims 44-48 are believed to be separately patentable, as is required in 37 CFR 1.192.

(8) Claims Appealed

Claims 49-51 have been indicated as being allowable and therefore are not appealed claims.

(9) Prior Art of Record

5,395,030	***Kuramoto, et al.***	***03-1995***
5,389,098	***Tsuruta, et al.***	***02-1995***
5,562,694	***Sauer, et al.***	***10-1996***
DE 4,006,673	***Kessel***	***09-1991***

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 36-38,40-44 and 46-48 are rejected under 35 U.S.C. 102(e). This rejection is set forth in a prior Office Action, mailed on 11-07-2003.

Claims 36-48 are rejected under 35 U.S.C. 103. This rejection is set forth in a prior Office Action, mailed on 11-07-2003.

Pursuant to the Remand under 37 CFR 1.193(b)(1) by the Board of Patent Appeals and Interferences on 04-29-2005, a supplemental Examiner's Answer is set forth below:

(11) Response to Argument

This application was remanded back to the examiner to issue a supplemental examiners amendment answering the arguments on page 4 and 5 of the reply brief filed on 11-04-2004. Applicant did not argue in the after final amendment of 02-26-2004 or the appeal brief of 04-30-2004 that Kuramoto did not disclose an operating capsule including a coupling structure for selectively coupling to a flexible endoscope. However, in response to the examiner's answer, the appellant now argues that Kuramoto does not disclose this feature. Appellant also states that the stapler/endoscope of Kuramoto is a structurally singular device with an endoscope which is an integrated component of the stapler/endoscope. ... that the endoscope is not separable from the stapler/endoscope. Further, there is no structure for coupling an endoscope to the device. The examiner contends that Kuramoto discloses many different embodiments of the endoscopic surgical stapler device. As shown in fig. 22 and 23, one of the embodiments with the grasping forceps 150, element 141 which includes an endoscope with an observation window 144 and a light source 145, is indeed releasably coupled to both components 136 and 146 of the capsule. Clearly, element 141 can slide relative to tube 136 and 137, and is therefore selectively coupled to by a coupling, ie. a lumen, and as shown in fig. 24, element 141 can be removed from anvil element 146. The examiner also contends that element 136 of the capsule is also selectively coupled to the end of tube 137.

Next, appellant argues that the forceps 150 could not draw tissue between the anvil and the stapler; and even if the forceps could grasp tissue, it would frustrate the

purpose of the Kuramoto device. This argument is not persuasive for several reasons. Firstly, whether it would frustrate the intended purpose of the device is irrelevant to this discussion. However, the examiner will address this argument later. All that is necessary is for the examiner to demonstrate that the forceps could be used to grasp tissue and draw it into the cutting zone. Secondly, the examiner contends that using the forceps to grasp tissue and draw it into the area between the cutter/stapler and anvil would be extremely simple. Noting fig. 22 and 23, at some point between fig. 22 and 23, the anvil shaft 147 would not have yet penetrated the fold of tissue at 114. At this point, the forceps could be placed to extend out hole 140 to grasp section 114 of tissue draw it into position between 138 and where the anvil will pierce through 114. The forceps could even be used to assist in holding the tissue still while the anvil pin 147 pierced through tissue 114. The examiner contends that this alone would read on the claim limitations of grasping a fold of tissue and drawing it into a cutting zone- the area between the anvil and stapler. Additionally, once the device is positioned as in fig 23, the forceps could be adjusted laterally by moving tube 136 laterally to a position whereby the forceps were aligned to the left of the pin 147. In such a position, the forceps could easily grasp another section of tissue, pull it over the pin and even cause the pin to puncture the new tissue, followed by using the forceps to grasp the pin147 and draw the pin to the stapler. Clearly, the forceps in this manner would be drawing tissue into the cutting zone. The forceps could even draw tissue to the point where it was contacting the annular face of the stapler and cutter. Indeed some tissues would be thin and elastic enough to be brought into hole 140, still grasped by the forceps jaws

allowing the forceps to cause tissue to be drawn into the cutting zone (even by appellant's definition), after the pin of the anvil entered hole 140.

The examiner still contends that any area or zone adjacent to the cutter is the "cutting zone". There is nothing in the claims to limit the cutting zone to be present "only when the anvil is coupled to the housing". There is also nothing in Kuramoto to define the cutting zone to be present only when the anvil is attached to the housing 138. The fact that cutting might only be able to take place when the anvil is attached to the housing 138 is not germane to the issue of what constitutes a cutting zone. Tissue drawn into an area adjacent the cutter by forceps, which after the anvil has been coupled to the housing 138 is cut with the cutter, has nevertheless been drawn into the cutting zone by the forceps.

With respect to the argument that Tsuruta does not disclose that a flexible member extends through the body and out a natural body orifice to the control handle, this is not found persuasive because this limitation is a functional limitation, or one of intended use. The fact that Tsuruta is disclosed as being used through an incision, it certainly could have been used in, or through a body orifice. The argument that Tsuruta does not disclose how one skilled in the art would make the insertion section flexible is not persuasive. Col. 34 clearly states that the insertion section can be made rigid or flexible. If flexible, the inner components are made flexible "so that they can bend, too.". Therefore, Tsuruta discloses making the insertion section flexible (bendable) and the inner actuators flexible (bendable). As endoscopic instruments have been known long before applicant's invention, one skilled in the art would have had no problem in

manufacturing the stapler in a flexible embodiment with flexible actuators. As previously stated by the examiner, the argument that Tsuruta teaches away from adding forceps is not persuasive as the only embodiment that this applies to is in fig. 46-50. Clearly, the embodiment of Tsuruta which the examiner is modifying is that of fig. 1-3. Please see the arguments by the examiner regarding the appropriateness of providing forceps on this embodiment on pages 5-6 in the first examiner's answer.

The examiner is not required to show a bodily incorporation of the forceps with the stapler of Tsuruta; however, if necessary, following the teachings of Sauer, the forceps would merely be inserted through a portion of tube 9 so that the forceps jaws could access the area between jaws 3 and 4 of the stapler. Obviously, the device of Tsuruta is capable of being used without forceps. The examiner maintains that Sauer teaches that forceps can be used to manipulate tissue to enter the stapling zone. Sauer could have been used without forceps by merely gripping the tissue directly by jaws 28,30; however, the internal forceps would allow for getting the tissue in exactly the right position prior to closing of the jaws on the morcellator. Internal forceps of Sauer placed inside the device of Tsuruta would allow for easier manipulation of tissue sought to be stapled by allowing drawing in of the tissue to the cutting/stapling zone between the jaws 3 and 4 of Tsuruta.

Appellant argues that Kessel could not be placed in the tube 8 of Tsuruta and that the statement in Tsuruta that the distal end of the cartridge can be seen through an endoscope does not mean that Tsuruta should include an endoscope therein. Again as stated above, the examiner does not need to show a bodily incorporation of the

endoscope in the tube 8 of Tsuruta. Clearly, one skilled in the art, if provided with motivation for providing the tube 8 with an internal flexible endoscope would dimension the tube and endoscope such that it could receive the endoscope. Therefore, the only question at hand is whether there is motivation to place an endoscope inside the stapler with forceps combination of Tsuruta and Sauer. Kessel discloses a flexible endoscope housed within a common sheath with a forceps. One skilled in the art would recognize that the endoscope would be used to see the tissue desired to be grasped by the forceps. Providing an internal endoscope in Tsuruta would enable the user to see the operative field such that the device would be capable of stapling and cutting the proper tissues.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Glenn K Dawson
Primary Examiner
Art Unit 3731

gkd
May 18, 2005

KENYON & KENYON
1500 K STREET NW
SUITE 700
WASHINGTON, DC 20005